01/16/2009

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# NOTICE OF ALLOWANCE AND FEE(S) DUE

151 7590

HOFFMANN-LA ROCHE INC. PATENT LAW DEPARTMENT 340 KINGSLAND STREET NUTLEY, NJ 07110 EXAMINER

KIM, ALEXANDER D

ART UNIT PAPER NUMBER

1656 DATE MAILED: 01/16/2009

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/816,708	04/02/2004	Wendy Lea Corbett	20892 US2	1192

TITLE OF INVENTION: CRYSTALS OF GLUCOKINASE AND METHODS OF GROWING THEM

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1510	\$300	\$0	\$1810	04/16/2009

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

#### HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

#### PART B - FEE(S) TRANSMITTAL

## Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE

Commissioner for Patents P.O. Box 1450

Alexandria, Virginia 22313-1450 (571)-273-2885 or <u>Fax</u>

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for

maintenance fee notifications. Note: A certificate of mailing can only be used for domestic mailings of the CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address) Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission. 151 7590 01/16/2009 Certificate of Mailing or Transmission HOFFMANN-LA ROCHE INC. I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below. PATENT LAW DEPARTMENT 340 KINGSLAND STREET NUTLEY, NJ 07110 (Depositor's name (Signature (Date APPLICATION NO. FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. FILING DATE 10/816,708 04/02/2004 Wendy Lea Corbett 20892 US2 1192 TITLE OF INVENTION: CRYSTALS OF GLUCOKINASE AND METHODS OF GROWING THEM APPLN. TYPE SMALL ENTITY ISSUE FEE DUE PUBLICATION FEE DUE PREV. PAID ISSUE FEE TOTAL FEE(S) DUE DATE DUE nonprovisional NO \$1510 \$300 \$0 \$1810 04/16/2009 **EXAMINER** ART UNIT CLASS-SUBCLASS KIM, ALEXANDER D 1656 435-194000 1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363). 2. For printing on the patent front page, list (1) the names of up to 3 registered patent attorneys ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached. or agents OR, alternatively, (2) the name of a single firm (having as a member a ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required. registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed. 3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type) PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment. (A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY) 4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above) 4a. The following fee(s) are submitted: lssue Fee A check is enclosed. Publication Fee (No small entity discount permitted) Payment by credit card. Form PTO-2038 is attached. The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number \_\_\_\_\_\_ (enclose an extra copy of this fo Advance Order - # of Copies \_ (enclose an extra copy of this form). 5. Change in Entity Status (from status indicated above) a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27. ■ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2). NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office. Authorized Signature Date Typed or printed name Registration No. This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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HOFFMANN-LA ROCHE INC.		KIM, ALEXANDER D		
PATENT LAW DEPARTMENT			ART UNIT	PAPER NUMBER
340 KINGSLAND STREET NUTLEY, NJ 07110			1656 DATE MAILED: 01/16/200	0

# **Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)**

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 644 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 644 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 (571)-272-4200.

	Application No.	Applicant(s)	
	Application No.	Approxim(5)	
Notice of Allowability	10/816,708	CORBETT ET AL.	
Notice of Anowability	Examiner	Art Unit	
	ALEXANDER D. KIM	1656	
The MAILING DATE of this communication appear All claims being allowable, PROSECUTION ON THE MERITS IS herewith (or previously mailed), a Notice of Allowance (PTOL-85) NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RI	(OR REMAINS) CLOSED in or other appropriate commu IGHTS. This application is so	this application. If not included nication will be mailed in due course. <b>THIS</b>	e
1. 🔀 This communication is responsive to the amendments filed	<u>1 09/05/2008</u> .		
2. ☑ The allowed claim(s) is/are <u>1-4</u> .			
<ul> <li>3.  Acknowledgment is made of a claim for foreign priority ur</li> <li>a)  All b)  Some* c)  None of the:</li> <li>1.  Certified copies of the priority documents have</li> <li>2.  Certified copies of the priority documents have</li> </ul>	e been received.		
3. ☐ Copies of the certified copies of the priority do	• • • • • • • • • • • • • • • • • • • •		
International Bureau (PCT Rule 17.2(a)).		m and national stage approation nom the	
* Certified copies not received:			
Applicant has THREE MONTHS FROM THE "MAILING DATE" noted below. Failure to timely comply will result in ABANDONN THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.  4. A SUBSTITUTE OATH OR DECLARATION must be submin INFORMAL PATENT APPLICATION (PTO-152) which give	IENT of this application. itted. Note the attached EXA	MINER'S AMENDMENT or NOTICE OF	
5. CORRECTED DRAWINGS (as "replacement sheets") mus		desidiation is denoted.	
(a) ☐ including changes required by the Notice of Draftspers		(PTO-948) attached	
1) ☐ hereto or 2) ☐ to Paper No./Mail Date		(110 540) attached	
(b) ☐ including changes required by the attached Examiner's Paper No./Mail Date	s Amendment / Comment or		
Identifying indicia such as the application number (see 37 CFR 1 each sheet. Replacement sheet(s) should be labeled as such in t			
6. DEPOSIT OF and/or INFORMATION about the depo attached Examiner's comment regarding REQUIREMENT			
Attachment(s)	E   Notice of Inf	ormal Datant Application	
<ol> <li>Notice of References Cited (PTO-892)</li> <li>D Notice of Draftperson's Patent Drawing Review (PTO-948)</li> </ol>		ormal Patent Application mmary (PTO-413),	
<ol> <li>Information Disclosure Statements (PTO/SB/08),</li> </ol>	Paper No./ľ	Mail Date Amendment/Comment	
Paper No./Mail Date4. ☐ Examiner's Comment Regarding Requirement for Deposit	8. ⊠ Examiner's 9	Statement of Reasons for Allowance	
of Biological Material	9. 🔲 Other	<u>.                                    </u>	

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## **DETAILED ACTION**

### Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 05 September 2008 has been entered.

#### Status of the Claims

2. Claims 1-4 are pending and subject to examination on the merits.

### Examiner's amendment to the Claims

3. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment shown below was given in a telephone interview with Robert P. Hoag on 15 January 2008.

Amend the claim listing filed on 09/05/2008 with the following changes.

Claim 3: Insert the term "Daltons" after the recitation of "about 10,000"; to make Claim 3 to recite ---about 10,000 Daltons---.

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#### Statement of Reasons for Allowance

4. Claims 1-4 are allowed. The following is an examiner's statement of reasons for allowance:

The instant invention is drawn to crystals of a fusion protein SEQ ID NO: 1 (i.e., GST-human glucokinase); and a process of preparing the crystals that is useful, for example, for studying glucokinase activators increasing the flux of glucose metabolism to treat type II diabetes (see instant specification, bottom of page 2).

The claimed glucokinase crystals (SEQ ID NO: 1) having specific unit cell dimensions, and P6(5)22 symmetry as noted in claims 1 and 2 are novel and unobvious in view of the unpredictability of forming such crystals even with a previously known enzyme. The crystals disclosed in Claims 1-2 are enabled by the use of the specific process disclosed by the applicants in Claims 3-4. In view of the examiner's amendment noted above and the approval of all necessary terminal disclaimers, all outstanding rejections are withdrawn.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance.

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#### Conclusion

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEXANDER D. KIM whose telephone number is (571)272-5266. The examiner can normally be reached on 11AM-7:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Alexander D Kim/ Examiner, Art Unit 1656

/SUZANNE M. NOAKES/ Primary Examiner, Art Unit 1656